

REMARKS

Claims 1-6 and 8-15 are pending. Claims 1 and 6 have been amended. Claims 3 and 8 have been cancelled. New claims 16-29 have been added. Support for new claim 16 is found in the specification as filed, *e.g.*, at claim 1 as filed & page 16. Support for new claims 17-29 is also found in the specification as filed, *e.g.*, at claims 2-15. No new matter has been added.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement. The Office asserts that the application “does not provide explicit support” for the use of the term “about” in connection with the recited range of ratios for the first and second polymers, and that the claimed limitation therefore allegedly constitutes new matter. Applicants request reconsideration of this rejection because the patent laws do not require explicit support for claim terms. *In re Anderson*, 176 U.S.P.Q. 331 (C.C.P.A. 1973) (limitations appearing in claims need not be literally recited in the specification; the issue is not whether words used in the claims are present in the specification but, rather, whether the concept expressed by the words is present). The decision of the Court of Customs and Patent Appeals in *In re Wertheim*, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976) is instructive. The invention in *Wertheim* related to a method of making decaffeinated coffee. Applicants' Swiss priority application described the use of solid contents in the range of 25-60% and set forth specific embodiments of 36% and 50%. Claims to 35-60% were rejected by the examiner and not accorded the priority filing date because the claimed range was not literally recited in the Swiss application. The Court, however, reversed the rejection, and stated that the absence of literal support in the specification for claim language is not enough to support a rejection under the description requirement of 35 U.S.C. § 112, first paragraph. *Id.* at 98. Citing *In re Smith*, 178 U.S.P.Q. 620 (C.C.P.A. 1973), the Court in *Wertheim* stated that:

The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material.

Id. at 96. The Court in *Wertheim* made it clear that the test for compliance with the description requirement is whether support for a claimed invention is generally found in the specification, not whether the claims are recited in the specification verbatim. Since there is no evidence of record suggesting that those skilled in the would not find Applicants' claim language to be at least implicitly supported by the instant disclosure, the rejection under Section 112 is improper and should be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 1-6 and 8-15 have been rejected under § 103(a) for alleged obviousness over WO 02/11694 A2 to Rosenberg *et al.* ("the Rosenberg publication") in view of WO 97/44014 to Baert *et al.* ("the Baert publication") or WO 99/33467 to Jung *et al.* ("the Jung publication"). Claims 1-6 and 8-15 have also been rejected for alleged obviousness over the Baert publication in view of *Matsumoto & Zografi, Pharm. Res. 16:11 (1999)* ("the Matsumoto publication") and the Jung publication. However, the cited publications, either alone or in combination, do not teach or suggest solid dispersions comprising the claimed polymers in the claimed ratios.

Although the Office has alleged that the ratio between the first and second polymers "would have been a matter of routine optimization" to one skilled in the art (3/39/2007 Office Action at pp. 7 & 11), this argument fails for several reasons. First, there is no evidence of record demonstrating a recognition that the percentage of polymer matrix incorporated into composition is a result-effective variable. M.P.E.P. 2144.05(II)(B) ("[a] particular parameter must first be recognized as a result-effective variable" before the determination of optimum or workable ranges of the variable may be characterized as routine experimentation) (quoting *In re Antonie*, 559 F.2d 618 (CCPA 1977)). Although the Office notes that "Rosenberg *et al.* uses various percentages of the different polymer matrices to prepare the compositions comprising itraconazole" (Office Action at page 7), this fact falls short of demonstrating the requisite recognition. Indeed, the authors of the Rosenberg publication experimented with many other possible experimental variables, and did not recognize the polymer ratio as being result-effective (*see, e.g.*, Example 1-3).

The second reason that the allegation regarding optimization fails is that the Rosenberg publication does not disclose or suggest varying the ratio of the two types of polymers that are recited in Applicants' claims. Example 1 of the Rosenberg publication, for example, uses a single polymer of the second type that is recited in the claims (*i.e.*, "a ... polymer that has a dissolution profile associated with the creation of a micro-environment enhancing the dissolution of the bioactive compound in an aqueous environment"), and Example 2 uses two polymers of this type. Only Example 3 involves the use of a polymer of the first type (*i.e.* "a ... polymer that allows a homogenous or molecular dispersion of the bioactive compound in the polymer matrix" such as N-vinylpyrrolidone vinylacetate copolymer) with a polymer of the second type (hydroxypropylcellulose). Significantly, however, the authors do not so much as suggest varying the respective percentages of the polymers used in Example 3.

Third, even if a *prima facie* case of obviousness had been established, it has been rebutted by Applicants' evidence of surprising results. M.P.E.P. 2144.05(III); *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004) (unexpected results relative to the prior art rebuts allegation of obviousness based on a claimed invention that falls within a range disclosed by the prior art). As Applicants demonstrate, for example, in FIG. 12, mere combination of the two recited polymers does not, in and of itself, provide the enhanced dissolution properties of the present invention. FIG. 12 shows that when the polymers are combined in a ratio of 60:40 or 20:80, they exhibit an additive effect, *i.e.*, the resulting mixture has an additive dissolution profile in that it lies between the respective dissolution profiles of the individual polymers. However, as shown in FIG. 13, combining the polymers in a ratio of 70:30 to 80:20 surprisingly results in a dissolution profile that is not merely additive and, in fact, is superior to either polymer. Applicants respectfully submit that, as demonstrated at least by these unexpected results, the combination of the first and second polymers at a ratio of 70:30 to 80:20 would not have been obvious over the cited art.

For at least these reasons, the rejections of claim 1 and its dependents under § 103(a) should be withdrawn. Applicants also submit that new claims 16-29 are in condition for allowance for at least the reasons discussed above.

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**PATENT
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37 CFR § 1.116**

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The foregoing represents a *bona fide* attempt to advance the present case to allowance. In view of the preceding, Applicants respectfully request withdrawal of the rejections of the claims, and further submit that the pending claims are in condition for allowance. If the Examiner has any questions, the Examiner is invited to call the undersigned at (215) 568-3100.

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